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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/175,713	10/20/1998	STEPHEN H. HERRMANN	GI-5302-CON	7226

7590 12/20/2001

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/20/2001

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/175,713

Applicant(s)

HERRMANN ET AL.

Examiner

Janet L Andres

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 October 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 18 October 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

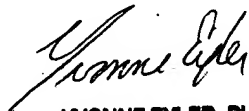
Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-14, 17, 18.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's amendment adding particular hybridization conditions is sufficient to overcome that part of the rejection of claims 6-9 under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "stringent hybridizing conditions". The claims, however, still encompass fragments, and as stated in the previous office action, there is no limitation on what activity is required and thus on what molecules are encompassed. Applicant has not provided further arguments or amendments addressing the rejection of claims 14, 17, and 18 under 35 U.S.C. 112, first paragraph, as lacking written description. As stated in previous office actions, the functional characteristics of only one species encompassed by the claims are disclosed. No structural relationships or essential characteristics of the claimed molecules are disclosed. Thus, no necessary common attributes or features by which one of skill could identify members of the claimed genus are disclosed, and one of skill in the art would not recognize that Applicant was in possession of the invention as broadly claimed. Applicant has additionally not provided arguments or amendments addressing the rejection of claims 1-14, 17, and 18, as lacking enablement commensurate with the scope of the claims. As stated in previous office actions, while the generation of modified molecules is art standard, Applicant has not provided guidance sufficient for one of skill to use the invention as broadly claimed. The claims encompass molecules with many different structures three distinct modifications, and the art teaches that the effects of amino-terminal modifications are unpredictable. Thus Applicant's presentation of one working example is not sufficient to allow one of skill in the art to predict which, if any, other molecules potentially within the scope of the claims could be used similarly. Without the ability to predict which of the many possibilities would actually have the desired function, it would require undue experimentation for the skilled artisan to use the invention as broadly claimed.

  
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